

REMARKS

In the Office Action, the Examiner maintained the previous objection to the specification based on improper use of various trademarks. In response, Applicant has amended the specification under 37 C.F.R. §1.121 in order to properly recognize the trademarks. No new matter has been added by these amendments to the specification. Therefore, Applicant respectfully requests removal of this ground of objection.

The Examiner next withdrew as moot the rejection of claim 9 under 35 U.S.C. §112, first paragraph, because Applicant canceled that claim. The Applicant thanks the Examiner for the withdrawal of the rejection.

The Examiner then rejected Claims 32, 34 and 36 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. More specifically, the Examiner stated that Claims 32, 34 and 36 recite an amount of binder including 0%, which is inconsistent with the parent claims. In response, Applicant has amended Claims 32, 34 and 36 to recite that the binder is present in a minimum amount of from more than 0%. Therefore, Applicant respectfully requests removal of this ground of rejection.

The Examiner then withdrew the rejection of Claims 1-3, 6, 7 and 20-22 under 35 U.S.C. §102(b) as being anticipated by Morella et al. (WO 94/05262) (“Morella” or “the Morella reference”) based on Applicant’s previous amendments and the cancellation of Claim 3. Applicant thanks the Examiner for the withdrawal of the rejection.

The Examiner then rejected Claims 32, 34 and 36 under 35 U.S.C. §102(e) as being anticipated by Kanios et al. (U.S. Pat. No. 5,719,197) (“Kanios” or “the Kanios reference”). In response, Applicant respectfully requests reconsideration and removal of this ground of rejection.

More specifically, Applicant believes that the Examiner has misapplied the disclosure of Kanios to the invention of the present application. As the Examiner recognizes, Kanios is concerned with topical administration of various pharmaceutically active agents. See Dec. 19, 2006 Office Action at page 4; see also Kanios at Col. 1, lines 28-30 and Col. 2, lines 22-23. Furthermore, Kanios teaches that its dosage form must be applied to the skin. See, e.g., Col. 2, lines 65-67 and Col. 12, lines 30-33.

In contrast, the claims of the present invention specifically recite that the pharmaceutical composition must be in an “oral” form. Nowhere in the Kanios reference is it taught, disclosed, mentioned, or claimed that the pharmaceutically active agent can be ingested by a patient. Thus, the Kanios reference cannot anticipate the claims of the present because it does not teach “each and every element as set forth in the claim[s]” of the present application.” MPEP §2131 (citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987)); see also *Hakim v. Cannon Avent Group, PLC*, 479 F.3d 1313, 1319 (Fed. Cir. 2007) (“‘Anticipation’ means that the claimed invention was previously known, and that **all of the elements** and limitations of the claim are described in a single prior art reference...Under 35 U.S.C. §102, **anticipation requires that each and every element** of the claimed invention be disclosed in a prior art reference.” (internal citations and quotations omitted) (emphasis added)). Therefore, Applicant respectfully requests removal of this ground of rejection.

The Examiner then withdrew as moot the rejections under 35 U.S.C. §103(a) of Claims 8-9 as unpatentable over Morella and Claims 11-14 and 17-19 as unpatentable over Morella in view of Kanios because the claims were cancelled. Applicant thanks the Examiner for the withdrawal of the rejections.

The Examiner then rejected Claims 1, 7 and 20-37 under 35 U.S.C. §103(a) as being unpatentable over Morella in view of Kanios. In response, Applicant respectfully requests reconsideration and removal of this ground of rejection.

More specifically, Applicant avers that the one of ordinary skill in the art would not find it obvious to combine the two references. The Morella reference is directed towards an **oral** pharmaceutical dosage form. See Morella at page 3, lines 7-9; see also Morella Abstract. In contrast, and as discussed above, Kanios is concerned with **topical** administration of various pharmaceutically active agents. Nowhere does Morella teach, suggest, or disclose that its teachings could be applied to a topical formulation. Similarly, nowhere does Kanios teach, suggest, or disclose that its teachings could be applied to an oral formulation. The expertise required of one in the field of oral dosage forms is different than the expertise required of one in the field of topical dosage forms. Thus, the two references would not be combined by one of ordinary skill in the art.

Even if it were obvious to combine the two references (which it is not), that which Applicant claims as the invention still would not be created. More specifically, Applicant claims

a controlled release oral pharmaceutical composition that requires an active ingredient in the core. While Morella does teach an oral formulation, it does not teach a core-based oral formulation; rather, Morella teaches a matrix formulation. Kanios, as noted above, teaches a topical formulation. Therefore, because neither Morella nor Kanios teach an oral formulation wherein the active ingredient is located in a core, even by combining the two references, that which Applicant claims as the invention would not be created.

Therefore, because the references are not properly combinable and because that which Applicant claims as the invention still would not be created even if the references *were* properly combinable (which they are not), Applicant respectfully requests removal of this ground of rejection.

The Examiner then withdrew as moot the rejections under 35 U.S.C. §103(a) of Claims 4 and 8-10 as being unpatentable over Morella in view of Curatolo et al. (U.S. Pat. No. 6,068,859) (“Curatolo” or “the Curatolo reference”) and Claims 4-5, 11-13, 15, 16 and 18-19 as being unpatentable over Morella in view of Acharya (U.S. pat. No. 5,686,094) (“Acharya” or “the Acharya reference”) because the claims were cancelled. Applicant thanks the Examiner for the withdrawal of the rejections.

The Examiner then rejected Claims 1-2, 4, 7 and 10 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4 and 7-9 of U.S. Pat. No. 6,174,548 in view of both Morella and Kanios. In response, Applicant is submitting herewith a terminal disclaimer. Therefore, Applicant respectfully requests removal of this ground of rejection. It should be noted, however, that Claim 4 is no longer pending in the present application as it was cancelled by Applicant in Applicant’s September 18, 2006 Amendment.

The Examiner then withdrew as moot the rejection of Claims 4-5 and 8-10 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-2, 4-11, 16 and 18-19 of U.S. Pat. No. 6,602,522 due to the cancellation of Claims 4-5 and 8-10. Applicant thanks the Examiner for the withdrawal of the rejection.

The Examiner next rejected Claims 1, 6-7, 21 and 22 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-2, 4-11, 16 and 18-19 of U.S. Pat. No. 6,602,522 in view of Kanios. In response, Applicant is submitting herewith a

terminal disclaimer. Therefore, Applicant respectfully requests removal of this ground of rejection.

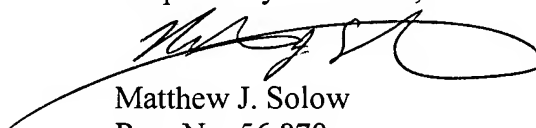
Next, the Examiner withdrew as moot the rejection of Claim 3 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4 and 7-9 of U.S. Pat. No. 6,733,778 in view of Morella due to the cancellation of Claim 3. Applicant thanks the Examiner for withdrawing the rejection.

The Examiner then rejected Claims 1-2, 5-11 and 13-16 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4 and 7-9 of U.S. Pat. No. 6,733,778 in view of Morella and Kanios. In response, Applicant is submitting herewith a terminal disclaimer. Therefore, Applicant respectfully requests removal of this ground of rejection. It should be noted that Claims 5, 8-11 and 13-16 are no longer pending in the present application as they were cancelled by Applicant in Applicant's September 18, 2006 Amendment.

Lastly, the Examiner requested that Applicant utilize proper Markush group language to indicate the group of drugs suitable for incorporation in Applicant's invented composition. In response, Applicant has amended Claims 1, 7, 20 and 21 in order to properly utilize correct Markush group language. Applicant apologizes for any inconvenience.

Based on the above, Applicant respectfully submits that the claims of the present invention are in proper form for allowance. Favorable consideration and early allowance are therefore respectfully requested and earnestly solicited.

Respectfully submitted,



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